

showed a strong trend for less CV-events ( $p = 0.098$ ). Cost-effectiveness of screening for elevated albuminuria was. €16,559/LYG (from €7,030 to €24,125 in sensitivity analysis). Stochastic analysis indicated that the probability of cost-effectiveness below the suggested Dutch threshold for cost-effectiveness of €20,000 per LYG is 60% in the baseline analysis, increasing to 91% if only those subjects are treated with foscipril showing a UAE >50 mg/24 hr. Also, limiting screening to only those aged greater or equal than 50; improved cost-effectiveness considerably. **CONCLUSION:** Primary prevention by screening the general population for the risk marker albuminuria greater or equal to 15 mg/24 hr and subsequent treatment with foscipril of those found positive to reduce the incidence of CV events may well be cost effective.

PUK9

#### **COST-EFFECTIVENESS OF PARICALCITOL IN THE TREATMENT OF SECONDARY HYPERPARATHYROIDISM: THE EXPERIENCE IN ITALY**

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**OBJECTIVES:** To evaluate short-term (12 months) cost-effectiveness (CE) of intravenous (iv) vitamin D preparations (paricalcitol and calcitriol) to control hyperparathyroidism in hemodialysis patients. **METHODS:** A decision analytic model was constructed and analysed from the hospital and the Italian National Health System (INHS) perspectives. Following the indications of the Italian Nephrology Society on the use of iv Vitamin D analogues, patients were simulated to start a 12-month iv Vitamin D treatment when parathormone (PTH) plasmatic level was >700 pg/ml. Starting doses were 27 µg/week for paricalcitol and 9 µg/week for calcitriol; subsequent maintenance dose was adjusted assuming decreasing PTH levels over time. Model parameters were derived from multiple published sources. Clinical course of treatment and efficacy in controlling hyperparathyroidism were based on a RCT (Sprague SM. *Kidney Int* 2003); effect on survival, hospitalisation rate and length-of-stay (LOS) were based on retrospective studies (Teng M. *NEJM* 2003; Dobrez DG. *Nephrol Dial Transplant* 2004). Cost included drug costs (hospital prices excluding taxes), cost per hospitalization (national mean DRG value, 2002), in the INHS perspective, or cost per day of hospitalization (general medical ward, Lucioni C. et al. *Treat Endocrinol* 2003), in the hospital perspective. **RESULTS:** Per patient one-year drug acquisition costs were €3364.74 for paricalcitol and 1883.25 for calcitriol. Calcitriol patients had an average of 0,846 hospitalizations/year more than paricalcitol at an incremental cost, in the INHS perspective (DRG tariffs), of €2868.69. Calcitriol patients had an average of 9.17 hospitalization/days more than paricalcitol at an incremental cost, in the hospital perspective (LOS), of €2249.58. Paricalcitol strategy resulted dominant in both perspectives. Robustness of these findings was demonstrated in multiple sensitivity analyses. **CONCLUSIONS:** In Italy, paricalcitol greater acquisition costs are offset by reduction in hospitalizations and LOS both from an NHS perspective and from the hospital perspective.

PUK10

#### **COST-EFFECTIVENESS OF MIMPARA AMONG DIALYSIS PATIENTS IN BELGIUM USING A MARKOV SIMULATION MODEL**

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**OBJECTIVES:** To demonstrate cost-effectiveness (ICER) of Mimpara (MIM), a drug against secondary hyperparathyroidism (sHPT) in dialysis, compared to standard treatment of care (SOC). **METHODS:** A Markov model operates in 1/2 year cycles and runs over 16 years until the starting cohort reaches 70 years. Mortality risk per cycle was calculated from a 2-year cohort dialysis database ( $n = 13,000$ )<sup>1</sup>. The model uses specific distributions for parathyroid hormone (PTH), Calcium (Ca) x Phosphor (P), age, vintage and MIM dosages (30–120 mg/day) from phase III trials. Patients withdrawing from MIM were treated with SOC. Average drug costs were €3109/year first cycle and €2617/year subsequent cycles as only drug responders (85%) remained on study drug. Other treatment costs were taken from a retrospective cost study in Belgium<sup>2</sup> using average daily cost of €214 per dialysis patient plus €50/day for sHPT-sufferer. Annual 3% discount rate was applied to cost and outcome data. **RESULTS:** Running the model in Monte-Carlo simulation (10,000 iterations) over 16 years, delivered a mortality difference of 0.17 years favoring MIM-use for an extra cost of €8027 (+ dialysis cost) resulting in an ICER of €47,218 per Life Year Gained. Excluding dialysis costs the ICER was €36,970. Sensitivity analyses ranging discount rates from 0% to 6% independently for both outcome and cost data showed ICERs of €36,970 and €59,459 for outcome and €64,517 and €35,088 for cost results, respectively. Evaluating the ICERs over time indicates that cost-savings may appear early in MIM-treatment (first 2 to 3 years) due to reductions in co-morbidities without observable survival benefit. **CONCLUSION:** Including dialysis costs in the ICER-equation maintained a reasonable CE-result (<€50,000/LYG) favoring the use of Mimpara for sHPT.

PUK11

#### **COST ANALYSIS OF RENAL REPLACEMENT THERAPIES IN LATVIA**

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**OBJECTIVES:** Kidney transplantation (KT) is generally acknowledged as the most clinically effective and cost-effective option in managing ESRD patients. The objective of our study was to identify costs and estimate cost-effectiveness of various ESRD treatment modalities in Latvia. **METHODS:** We retrospectively analysed files of 250 patients in an in-center hemodialysis treatment mode (HD), 60 patients in continuous ambulatory peritoneal dialysis treatment mode (CAPD) and 51 patients after successful KT for the first 3 years of treatment. All direct medical costs were registered. Cost-effectiveness was estimated by costs per 3 life-years gained. **RESULTS:** Mean direct costs (in 2003 €) for one patient for the first year and all three years of treatment were: for CAPD 16,250.0 + €1,577.4 and 48,327.7 ± 1, €162.2 respectively, for HD 14,131.7 ± €1,212.4 and 42,052.4 ± €1,203.2 respectively, and for KT 15,880.0 ± €4,744.7 and 25,460.0 ± €2,994.4 respectively. Average treatment costs per patient over the 3 years were the highest in the CAPD group ( $P < 0.05$  vs. HD,  $P < 0.001$  vs. KT) and KT was the least expensive (as expected). The initial higher costs of KT were fully recouped within 15 months after surgery. Probability of life expectancy for CAPD, HD and KT for the first and third year were: 77.3%, 84.1% and 91.3% respectively, and 45.0%, 43.1% and 83.7% ( $P < 0.001$  vs. CAPD and HD), respectively. The cost of 3 life-years gained by KT was significantly less ( $P < 0.001$ ) than the cost associated with CAPD and HD (€29,598.5 vs. €106,661.1 and €97,798.5 respectively). **CONCLUSIONS:** Compared to CAPD and HD, KT provided greater survival ben-

efits to patients with ESRD, at a lesser cost. It may be more cost-effective to manage patients starting on RRT with preemptive KT or HD, than CAPD.

#### PUK12

##### **ASSESSING THE EFFICIENCY OF INTERSTIM® IN FECAL INCONTINENCE (FI) IN THE SPANISH SETTING. A COST-EFFECTIVENESS SIMULATION MODEL**

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Fecal incontinence (FI) is one of the most psychologically and socially debilitating condition in an otherwise healthy individual. Sacral Nerve Stimulation (SNS) is the option in cases where conservative treatments have been ineffective and before undergoing surgery procedures like dynamic graciloplasty or artificial anal sphincter in patients with intact anal sphincter (IAS) and before Sphincteroplasty in patients with structural deficient anal sphincter (SDAS). Interstim® is a relatively new effective and safety therapy that has shown to be more effective than surgery in almost all patients. **OBJECTIVE:** To assess the efficiency of introducing Interstim® in management of patients suffering FI in the Spanish setting using a cost-effectiveness model. **METHODS:** A decision analytic model was developed to estimate the costs and outcomes of patients with FI managed with and without Interstim®. Clinical and economic data were retrieved from published studies and an expert panel. The analysis was run over a 5 years time horizon from a NHS perspective and the primary outcome was quality-adjusted life years (QALYs). Cost data were obtained from SOIKOS™ Spanish's health care costs database. Costs and benefits were actualized to euros 2004 and discounted at 3% annum. Sensitivity analyses were performed in order to handle uncertainty. **RESULTS:** Preliminary results show that the introduction of Interstim® in the management of FI increases treatment costs in 1211 in IAS patients and 1024 in SDAS patients (5246 to 6456 and 7648 to 8671 respectively), yielding to improvement in quality adjusted life expectancy of 0.234 and 0.228 respectively. Discounted cost per QALY gained of the introduction of Interstim® are 5182 and 4486. **CONCLUSIONS:** The use of Interstim® as an alternative to current surgical procedures in certain circumstances (as second or third treatment line in IAS and SDAS IF patients) is associated to an improvement of IF patients at a reasonable extra cost.

#### PUK13

##### **COST-MINIMISATION-ANALYSIS ON THE TREATMENT OF URINARY INCONTINENCE WITH TROSPIMUM CHLORIDE IN COMPARISON WITH OXYBUTYNIN IN GERMANY**

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**OBJECTIVES:** To compare both drugs in terms of efficacy and costs. **METHODS:** The efficiency of incontinence treatment, as perceived by third party payer, will be calculated. Due to comparable efficacy, a cost-minimisation-analysis was conducted to evaluate the costs of a treatment of urinary incontinence with trospium chloride and with oxybutynin. Based on data obtained from literature, a decision tree model was compiled to portray the course of treatment. Adverse drug reactions (ADR) were also be considered. Costs for treatment of incontinence, treatment of ADR, and for second-line therapy taken if the treatment failed, will be taken into consideration. After calculation of all the emerged costs, total costs were determined by means of the DATA-program. To analyse the influence of different parameters on total costs, from the perspective of the statutory health insur-

ance, two sensitivity-analyses were conducted. **RESULTS:** Trospium chloride caused third party payer expenses amounting to €2,032, whereby the expenses for oxybutynin were €1968. Because of the higher drug costs of trospium chloride, the treatment costs were accordingly 3.3 % higher. The model was proven robust. **CONCLUSION:** Treatment of urinary incontinence with trospium chloride is as efficacious as the well-established oxybutynin and costs are comparable despite the higher price of trospium chloride. The advantages however of trospium chloride over oxybutynin are obvious by its adverse event profile—the risk of ADR is reduced. From the above mentioned facts, it may be concluded that the treatment of urinary incontinence with trospium chloride offers an adequate treatment alternative from the perspective of the statutory health insurance in Germany.

#### PUK14

##### **COST OF ILLNESS OF FEMALE LOWER URINARY TRACT SYMPTOMS (LUTS)**

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**OBJECTIVES:** Since 1992, legislative actions were taken to face the increasing pharmaceutical expenditure in Italy. In this context, evaluating the cost of illness on the NHS and the patient becomes crucial, especially for high prevalence conditions, like females LUTS. **METHODS:** This economic evaluation is part of the FLOW project, a 2-year observational study aimed at evaluating the frequency and clinical progression of symptoms in Italian women suffering from LUTS for ≥3 months presenting at 39 Urology Centres. Data on NHS expenditure such as specialist visits, hospitalization, therapy and laboratory tests were collected retrospectively between May 2002 and May 2003. Direct costs sustained by patients were collected using the Dowell-Bryant Incontinence Cost Index (DBICI) which investigates costs of disposable pads, re-usable incontinence products, laundry expenditure, health professional expenditure, surgery/diagnostic investigation and medication. **RESULTS:** Costs sustained by NHS: After a one-year follow-up, 550 women [mean (SD) age = 53.5 (13.8) years] were evaluated. The direct yearly total cost for this cohort was €284,943,08. Of the total expense, more than half (50.8%) was devoted to surgical therapy, 30% to laboratory and instrumental tests and 12.5% to rehabilitative therapies. The estimated annual average direct cost per patient with LUTS was €518,08. For the urinary incontinence (UI) group the annual expense was €635,00. Costs sustained by patients: 200 women with UI compiled the DBICI. Estimated annual average expenditure per patient was 276.04 euro. Of the total personal expenditure, the disposable incontinence products accounted for 38% and medication for 22%. **CONCLUSION:** In Italy, little is known about the economic impact of LUTS. UI seems to be the most expensive LUTS problem from the NHS point of view. Diapers and medication represent the most expensive products for the patient.

#### PUK15